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## Trying to fill a hole in clinic regulation

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In 2007, a state appeals judge handed a Southern California orthopedist named Daniel Capen a victory in his quest to build his own outpatient medical clinic without obtaining a license from state health regulators.

California's ability to regulate doctors and outpatient clinics still has not recovered.

In ruling for Capen, the court stripped what is now the state Department of Public Health of its jurisdiction over clinics owned by doctors. The agency retained its authority only over hospitals and non-doctor owned clinics. Everything else became the responsibility of the Medical Board of California. That's a problem, because the medical board has no expertise in inspecting or regulating surgical facilities.

If you suspect that the court decision opened a loophole one could drive a fleet of ambulances through, you'd be right. According to the medical board's most recent reckoning, more than 700 clinics statewide are exempt from state licensing.

As my column Wednesday pointed out, we know almost nothing about the general quality or safety of these physician-owned facilities. The medical board has no authority to stage surprise inspections, and no power to shut down a clinic if it believes it's dangerous.

The board vests inspection power in four nonprofit independent accreditation organizations; if any one of them accredits your clinic, you're good to go. But the organizations don't apply the same standards and don't coordinate their oversight. This leads to "accreditation shopping," in which a clinic that gets revoked or refused accreditation by one of these bodies can simply apply to another.

No other state divvies up the oversight of outpatient clinics between two agencies, only one of which is qualified to do the job, according to a 2009 Rand Corp. study.

This is just one more illustration of how California's system of medical regulation reflects years of broken promises and unconscionable legislative delay. In 2004, Julianne Fellmeth, a San Diego public interest lawyer then serving as a legislatively appointed monitor of the medical board's enforcement program, documented the history, which began with the Medical Injury Compensation Reform Act of 1975.

MICRA was a harsh anti-tort law pushed by doctors and malpractice insurers to address a largely fabricated malpractice "crisis." In return for making malpractice cases almost impossible to file, the medical profession promised to accept tougher disciplinary standards from the state. These were then in the hands of a board of medical examiners largely uninterested in physician discipline. But by the time these changes got through the legislative wringer, the legal barriers to license revocation or other serious punishment were heightened, not lowered.

Every now and then Sacramento would take another stab at tightening enforcement. But typically it took away with one hand what it granted with the other. It mandated that hospitals and licensed clinics report to regulators any adverse actions taken against a staff doctor, such as revocation of privileges -- but it closed those reports to public scrutiny, even though they're considered to be among the best indicators of physician unfitness.

As a result, if you're operated on at a plastic surgery or weight-loss clinic by a doctor who was bounced from the staff at a hospital for unfitness, the former hospital will know, your clinic will probably know and the state will know, but you can't know.

The case for regulation and disclosure is made by a wrongful-death case reported by my colleague Molly Hennessy-Fiske last year.

Hills Surgical Institute of Anaheim Hills was not accredited when a patient named Maria Garcia had plastic surgery as an outpatient there in 2008, according to the medical board. She died at a hospital later that day.

Two doctors her family identified in a wrongful-death lawsuit as having been involved in her treatment have since been disciplined by the medical board, with one accepting a 35-month probation during which he can't perform surgeries, and the other surrendering his medical license. The family has settled its lawsuit, according to court records.

For nearly four years, the Legislature and Gov. Arnold Schwarzenegger dithered over how to close the enforcement gap opened by the Capen decision -- whether to restore all authority to the public health department or close the loopholes in the accreditation process. The good news is that we may be finally on the verge of a solution. Senate Bill 100, introduced by Sen. Curren Price Jr. (D-Inglewood) and now making its way through the legislative process, would do much to achieve the latter.

"For any death to occur or any harm in a fashion that suggests there's careless disregard is an outrage," Price told me. "The state's got to step in and be proactive."

Among other things, Price's measure would:

- \* End accreditation shopping by mandating that any one organization's revocation of a clinic be honored by the others
- \* Require that an accreditation body inspect a clinic within five business days of receiving a safety complaint
- \* Require that any revocation, suspension or reprimand of a clinic be made public within 24 hours, and that all inspection reports be available for public view, along with a list of all clinics, their owners and their medical license status
- \* Give the board the authority to make unannounced inspections, and to move for an injunction in court to shut down an outpatient facility that doesn't meet standards

What's stunning is that the board doesn't have these powers already.

To see how they would work in practice, let's examine the case of Almont Ambulatory Surgery Center, a Beverly Hills outpatient clinic specializing in weight-loss surgery.

For a few months in 2009, the center was accredited by the American Assn. for Accreditation of Ambulatory Surgery Facilities. The organization revoked Almont's accreditation in April that year, after its inspectors followed up on a safety complaint.

That action wasn't known to Willie Brooks Jr., a Pomona school custodian who had a laparoscopic gastric band implanted there a few weeks later. Brooks died three days after the operation from what the Riverside County coroner identified as "peritonitis due to lap band procedure due to obesity."

If SB 100 in its current form were the law then, Brooks would likely have learned about the revocation before having surgery. He might also have learned that less than a month before his operation, state health inspectors had visited the facility and written a 22-page list of health and safety deficiencies; these were serious enough for federal Medicare officials to conclude that they posed "immediate jeopardy to the health and safety" of its patients, and to withdraw the clinic's right to treat Medicare enrollees.

Brooks' family says in a lawsuit that the clinic didn't tell them about the inspection results. Had he known, Brooks might have chosen to have surgery elsewhere, and who knows -- he might be alive today.

If SB 100 were the law in July 2009, the Joint Commission, another of the four independent accreditation agencies empowered by the medical board, might have thought twice before accrediting a facility called Beverly Hills Surgery Center, which had taken over Almont's location. It would have had no excuse for not knowing that the owners of Beverly Hills Surgery Center were Julian and Michael Omid, that the medical board had revoked Julian's license and placed Michael's on probation, and that they had been involved with launching and managing Almont.

Maybe the Joint Commission would have found justification for accrediting Beverly Hills anyway. But it might have been led to wonder whether it was accrediting a clinic that had previously had its accreditation revoked

by a different organization and was now just operating under a new name.

By the way, Los Angeles County coroner reports have stated that two other patients have died within days of receiving weight-loss operations at that clinic -- while it's been under Joint Commission accreditation. Robert Silverman, a lawyer for the facility, has defended the care that the deceased patients received there, and noted that none of the patients died on the premises.

The potential for a flood of deaths and injuries from poorly regulated outpatient clinics has loomed ever since the Capen decision. We stand now on the edge of the water. How bad does the crisis have to get before the Legislature finally acts?

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